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Award Number: DAMD17-98-1-8082

TITLE: Impact of BRCA1/2 Testing on Marital Relationships

PRINCIPAL INVESTIGATOR: Sharon L. Manne, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

REPORT DATE: June 2002

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 074-0188*



| 1. AGENCY USE ONLY (Leave blank) | 2. REPORT DATE | 3. REPORT TYPE AND DATES COVERED |
|---|---|---|
| | June 2002 | Final (4 May 98 - 3 May 02) |

**4. TITLE AND SUBTITLE**
Impact of BRCA1/2 Testing on Marital Relationships

**5. FUNDING NUMBERS**
DAMD17-98-1-8082

**6. AUTHOR(S)**
Sharon L. Manne, Ph.D.

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

**E-Mail:** sl_manne@fccc.edu

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**10. SPONSORING / MONITORING AGENCY REPORT NUMBER**

**11. SUPPLEMENTARY NOTES**

**12a. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**12b. DISTRIBUTION CODE**

**13. ABSTRACT** ***(Maximum 200 Words)***

This study examined the impact of genetic testing for breast-ovarian cancer susceptibility on marital relationships and the quality of life of partners, as well as an examination of how partner responses influence participant distress during the testing process. Participants were members of families in which a disease conferring mutation was been identified and their partners of either gender. Interviews of couples were completed by telephone prior to receiving test results, as well as 1-, 6-, and 12-months after test disclosure. Results indicated that participants who received negative results report decreases in IES scores over the six month period after disclosure of test results, while participants notified that they were carriers of the BRCA genes did not show a significant decrease in IES scores over the same time period. Partners did not evidence significant changes in either distress. Participants who rated higher levels of relationship strain associated with the testing process reported significantly more distress. Participants who rated their partners as responding in an unsupportive manner also reported more distress. Results suggested that the psychological impact of genetic testing on spouses was not significant. However, how partners respond plays a key role in how testing participants handle the genetic testing process.

| 14. SUBJECT TERMS | 15. NUMBER OF PAGES |
|---|---|
| breast cancer, BRCA1/2 testing, psychological outcome, marital relationship, social constraints | 16 |
| | 16. PRICE CODE |

| 17. SECURITY CLASSIFICATION OF REPORT | 18. SECURITY CLASSIFICATION OF THIS PAGE | 19. SECURITY CLASSIFICATION OF ABSTRACT | 20. LIMITATION OF ABSTRACT |
|---|---|---|---|
| Unclassified | Unclassified | Unclassified | Unlimited |

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## INTRODUCTION

The *Impact of BRCA1/2 Testing on Marital Relationships* was a prospective longitudinal study designed to examine the impact of genetic testing for breast-ovarian cancer susceptibility on the marital relationships of persons risk as well as the impact upon the quality of life of their partners. This study was a companion proposal to an ongoing, DOD-funded prospective study that evaluated the outcomes of genetic testing for breast-ovarian cancer susceptibility on women from hereditary breast cancer families (M. Schwartz, Principal Investigator, Georgetown University Medical Center). This study extended the ongoing DOD-funded study to examine the impact of genetic testing upon the marital relationship and the psychosocial impact on the partner. Specific aims of this study were: 1) to evaluate the short- and long-term impact of BRCA1/2 testing on psychological distress (both general and cancer-specific) of partners of participants in genetic testing programs; 2) to evaluate the short- and long-term impact of BRCA1/2 testing on the marital relationships of participants and partners, and examine whether marital satisfaction was an early predictor of psychological morbidity among participants in genetic testing programs and their partners; 3) to examine the association between spouse responses during the testing process and carriers' distress post-notification.

### Background and Study Rationale

Recent molecular studies have led to the identification of a major breast-ovarian cancer susceptibility gene, called BRCA1 (Miki et al., 1994). About 5-10% of all breast cancer cases are attributed to BRCA1 mutations. Healthy women who have inherited BRCA1 mutations have 80-90% lifetime risk of breast cancer and 40-65% risks of ovarian cancer (Easton et al., 1993). Among women who are affected with breast cancer, those with BRCA1 mutations are believed to have a 38% 10-year risk and a 65% cumulative risk of second primary breast cancers (Easton et al., 1995). A second susceptibility gene (BRCA2) is estimated to account for an additional 5% of breast cancer cases (Wooster et al., 1995) and is also associated with an elevated risk of ovarian cancer (Berman et al., 1996; Thorlacius et al., 1996). The prevalence of mutations in BRCA1 and BRCA2 is higher in certain subgroups of breast cancer patients, such as Jewish women, younger women and those with family histories of cancer.

Evaluations of the psychosocial impact of BRCA1/2 testing indicate that, although BRCA1/2 testing may not generate significant psychological morbidity (Lerman et al., 1996), a subset of gene mutation carriers may be vulnerable to test-related psychological distress (Croyle et al., 1997). As yet, nothing is known about the impact of BRCA1/2 testing on husbands of testing participants. Spouses may be vulnerable to psychological distress for several reasons. First, if the couple has children, the husband may worry about the threat of a possible altered breast cancer gene passed on to the children. If the couple is still planning on having children, the husband may have concerns about future childbearing. Indeed, our prior research suggests that concerns about implications for altered breast cancer gene passed on to children are important to high-risk women (Lerman et al., 1995) and that testing may impact on reproductive plans (Lerman et al., 1994).

Second, a husband may worry about the later development of cancer in his wife. The expectation of caregiving to an ill spouse, as well as worry about possible loss of the wife to cancer may each cause distress. Third, if the wife is distressed by the risk notification, her distress is likely to be conveyed to her spouse and is likely to lead to the husband becoming distressed. Indeed, studies of cancer patients and their spouses have suggested that spousal distress levels are highly correlated (Northouse, 1988).

In addition to impacting husbands' distress, genetic testing may place strain on the marital relationship. Our pilot data indicate that most couples discuss decisions (e.g., whether or not to undergo testing). Difficulty in communication during these discussions can result in less satisfaction with the marital relationship for both partners. Our prior research among cancer patients suggests that, if the patient feels constrained in his or her

ability to talk with the spouse about emotional concerns, this leads to decreased marital satisfaction and psychological distress for patients (Manne et al., 1997; Manne et al., 1997). A second source of marital strain may be the support-related interactions between women and their spouses. Individuals typically seek support from their spouses when they are distressed and unsupportive responses by spouses are a main determinant of marital dissatisfaction (Gottman et al., 1989). If genetic testing participants do not receive the expected spousal support, marital strain is likely. In addition, couples who begin the testing process with marital problems may be particularly vulnerable to increased marital strain when they receive notification of a genetic mutation. Most of the psychological literature dealing with families at high risk for breast-ovarian cancer focuses on either the affected individual or the person genetically at risk (Lerman et al., 1996; Croyle et al., 1997). Almost no attention has been paid to the spouse of the individual at risk or the spouse's response to notification of carrier status. There are a limited number of studies which examine the psychological impact on spouses of predictive testing programs for Huntington's disease (HD) which indicate that partners of HD carriers experience marital distress (Codori et al., 1994; Quaid et al., 1995; Tibben et al., 1993). Tibben et al. (1997) found that partners had similar patterns of psychological distress over a 6-month follow up compared to tested individuals. Both carriers and their partners evidenced distress returning to pretest levels over the 3 year follow up. However, among noncarriers, different patterns were found for carriers and their partners. Whereas noncarriers' partners had significantly lower levels of intrusive thoughts and avoidance at the 3 year follow up, the levels of intrusive and avoidant thoughts were at pre-test levels for noncarriers themselves. Partners of carriers who had children were more hopeless and distressed than partners without children, illustrating the important role of worries about children. Given that the illness course of HD is difficult and disease prevention is not possible, it is not known whether similar psychological responses occur among partners of BRCA carriers.

**Significance of the Study**

As yet, the impact of genetic testing for breast cancer on spouses or on the marital relationship has not been studied. This study was the first to examine psychological outcomes for partners. In addition, prior work has not examined the role of the partners=s support/lack of support on the participant=s psychological responses to the genetic testing experiences. Our studies of breast cancer patients indicated that women who experience many breast cancer worries and feel constrained in their ability to talk to their spouse are more likely to have emotional distress during their treatment. The proposed study examined this possibility among high risk omen who receive positive results for mutations in BRCA1/2.

We anticipated that this research would make several important contributions to the empirical literature as well as have implications for genetic testing programs. First, although it is well-known that carrier notification has implications for the whole family, the majority of studies to date have examined the impact at an individual level, neglecting effects on family members. This study would quantify the impact on the spouse, and identify those spouses who are vulnerable to a poor psychological outcome after testing. Distressed spouses may benefit from adjunctive psychological support during the testing process. Second, the results may have implications for genetic testing programs. If disclosure of results causes marital strain for some participants, then participants might benefit from the inclusion of spouses in disclosure sessions or training in more effective methods of facilitating disclosure of results. Identification of couples Aat risk≅ for marital and psychological strain during this process can be facilitated. Third, those participants with low levels of spousal support might be targeted for adjunctive therapies that bolster social support. This information would help providers anticipate and more effectively deal with problems that may arise in clinical genetics programs.

In addition, this research would have important implications for the way in which genetic counseling and testing programs are currently being conducted. If disclosure of results causes strain for some participants, then participants might benefit from the inclusion of spouses in disclosure sessions or training in more effective methods of facilitating disclosure of results to family members. If mutation carriers who have more distressed

marriages at the onset of the testing process or carriers who perceive more constraints in their ability to talk with their husbands about concerns related to breast cancer are particularly vulnerable to poor psychological outcomes, these participants can be identified early and these women can be offered adjunctive therapies that bolster social support from other sources, or offered marital counseling. The information provided by this study would assist genetic testing providers to anticipate and more effectively deal with problems that may arise in clinical genetics programs.

**Preliminary Studies**

*Lerman et al. (1996)* examined 279 members of breast-ovarian families and found that noncarriers of BRCA1 mutations showed significant decreases in depression compared to carriers and decliners of testing one month post-notification (1996). There were no significant changes in carriers or decliners. These results indicate that, at least in the short term, the majority of high risk individuals do not evidence significant psychological distress. However, there was variability in the distress measure, indicating that education or other psychological factors might contribute to differences in psychological impact of testing. This study also did not identify individual differences in responses to testing, including the impact on family relationships.

*Manne* conducted a pilot study of 20 high risk women participating in the genetic testing program for breast-ovarian cancer at Memorial Sloan-Kettering Cancer Center. Women were administered questionnaires pre-genetic counseling, one month post-genetic counseling and one month post-test notification (1/14 tested positive). Pre-counseling: 90% of women discussed the decision to seek testing with their spouses and sought spouse advice. On average, spousal advice was rated as having Asomewhat≅ of a role in the testing decision. Most women planned to disclose results to their husbands (90%). On average, participants anticipated a little difficulty in sharing results and felt husbands would be Asomewhat≅ supportive during the discussion of test results. Post-counseling results indicated that most participants discussed the results of the counseling session with their husbands. On average, they rated their spouses as Asomewhat≅ supportive and felt the process had placed Aa little≅ strain on the marital relationship. A subsample of 20% of participants reported that their spouses had avoided discussing the issue and reported that the process placed some strain on the relationship. One month post-notification: only 1/14 participants were carriers (too small for statistical comparisons). All but one of the women had disclosed results to their spouses. Whereas marital strain imposed by testing was relatively low in the majority, 30% stated their spouses Asomewhat avoided≅ discussing the testing and half rated their spouses as Asomewhat supportive≅ (3 on a 5 point Likert scale).

**BODY**

**Technical Objectives**

We conducted a prospective study to evaluate the impact of genetic testing for breast-ovarian cancer susceptibility on the marital relationships of persons at risk as well as the impact upon the quality of life of their partners. This study was a companion proposal to an ongoing NIH-funded evaluating the outcomes of genetic testing for breast-ovarian cancer susceptibility on women from hereditary breast cancer families (M. Schwartz, Principal Investigator, Georgetown University Medical Center). The proposed study extends the ongoing NIH-funded study to examine the impact of genetic testing upon the participants' perceptions of the marital relationship and the psychosocial impact on the partner. The initial study aims were:

*Aim 1: To evaluate the short- and long-term impact of BRCA1/2 testing on psychological distress (both general and cancer-specific) of partners of participants in genetic testing programs.* At 1- and 6-months post-notification, partners of participants who have a confirmed BRCA1/2 mutation will have increased

psychological distress (general and cancer-specific) compared with partners of non-carriers (NC) and test decliners (TD). At 12 months, there will be no differences between the three groups.

*Aim 2: To evaluate the short- and long-term impact of BRCA1/2 testing on the marital relationships of participants and partners, and examine whether marital satisfaction is an early predictor of psychological morbidity among participants in genetic testing programs and their partners.* It was hypothesized that, at 1- and 6-months post-notification, husbands of women who have a confirmed BRCA1/2 mutation (Mc) will have decreased marital satisfaction compared with husbands of non-carriers (Nc) and test decliners (Td). At 12 months, there will be no differences between the three groups. It was hypothesized that, for participants with high levels of marital satisfaction at baseline, marital satisfaction will not change significantly from pre- to post-notification (Mc, Nc, Td). For participants with low levels of marital satisfaction at baseline, carriers= marital satisfaction will decrease over the one year follow-up whereas noncarriers= and decliners= marital satisfaction will not change over the 1 year follow-up. Similar predictions are made for partners.

*Aim 3: To examine the association between partner responses during the testing process and carriers= distress post-notification.* Carrier participants who evidence high levels of cancer-related worries and experience more constraints in their ability to talk to their partners about the testing experience will evidence more psychological distress and lower marital satisfaction at 1-, 6- and 12-months post-notification.

## Methods

*Overview of Study Design*

Parent study (M. Schwartz, Principal Investigator). The parent study was ongoing at Georgetown University Medical Center. All women recruited for the parent study were recruited from this study site. In this prospective longitudinal study, eligible persons were invited to participate in a baseline telephone interview. Subsequently, they were invited to participate in a Pre-Test education session and are offered a test for the BRCA1 mutation known to be segregating in their family. The results of this test were presented at an individual genetic counseling session. All participants received follow-up phone interviews at 1-, 6-, and 12-months post-disclosure. Persons who agreed to participate in the study but decline Pre-test education and/or mutation status determination received the same telephone interviews. Analyses compared mutation carriers, noncarriers and participants who declined testing.

*Participants*

Eligibility criteria

Familial risk subjects. Persons eligible for this study were married or cohabitating individuals, ages 18 and older who were members of HBOC families in which as disease conferring mutation has been identified, and their partners of either gender. We estimated that about 30% of the sample would be affected (statistical analyses will control for status-affected vs. at-risk). Subjects were ineligible for this study if either they have a psychiatric or cognitive disorder that precluded informed consent.

Accrual estimates. We initially estimated the following: Five women per week would be eligible for participation. We estimated that seventy percent of the pool of 650 women would be married or cohabitating (N= 455). Of these 455, 30% (137) would decline mutation status testing. If 318 persons elect to receive test results, about 145 (32%) would be mutation carriers and 172 (38%) noncarriers (there are more non-carriers since some subjects will be at 25% risk). Ten percent of participants drop out of the study by the one year follow-up, with a final sample size of 410: N, carrier group=130, N, noncarrier group=152, N, decline

testing=130. Partners would be eligible for the study even if their partner declined participation (this is relevant to sample size for Aim 3). From the PI=s ongoing study of couples with cancer, it was anticipated that 10% of partners would decline participation. Thus the final sample size of partners was estimated to be 370 (of which 110 are carrier couples). We expected that 65% of subjects will be white, 25% African American, 5% Hispanic, and 5% Asian/Pacific Islander or Native American.

*Procedures*

All study procedures for familial risk subjects were conducted at Georgetown University Medical Center. After informed consent was received from the participant and consent was given to contact the participant=s partner, the partner's name, address and telephone number was provided to the Research Study Assistant at Fox Chase Cancer Center by the Research Study Assistant at Georgetown. All study procedure activities for partners were conducted at Fox Chase Cancer Center.

Identification of subjects. Procedures for identifying eligible HBOC families were described in detail in the funded DOD parent grant. We will provide an abbreviated description of study procedures and focus more on partner recruitment procedures.

Recruitment of participants. Procedures were being used in the ongoing study that forms the basis for this proposal. Informed consent procedures were consistent with the guidelines of the NIH/National Center for Human Genome Research (NCHGR) Cancer Studies Consortium.

Recruitment of spouses. The introductory letter included a description of the desire for partner participation and a rationale for the inclusion of partners in the study. When women were contacted for oral consent for the baseline telephone interview, permission to contact the spouses was obtained. It was stressed that permission to contact spouses was not a requirement for participation in the individual portion of the study. A letter was sent to partners immediately after permission is given to contact them. Written informed consent for the telephone interviews with the partners was obtained.

Assessment Procedures for Familial Risk Participants

Baseline Telephone Interview: Telephone interviews were used successfully in ongoing data collection. A subset of the measures already being administered in the parent DOD-funded study was used for data analyses in the current study. These measures were: cancer-specific distress (RIES), general distress (Hopkins Symptom Checklist-25), and general family relationship quality (Family Relationship Inventory). The following additional measures were administered (see measures for complete description): partner support and encouragement for genetic testing, whether or not decision to seek testing was discussed with the partner, plans to disclose test results to the partner, degree of strain/positive impact of testing process on marital relationship, degree of desire to talk about genetic testing, actual talking about genetic testing, perceived negative behaviors engaged in by the partner, partner protective buffering, closeness of the marital relationship, and marital satisfaction. Participants who declined testing filled out a subset of the measures that were relevant to them (distress, marital satisfaction, family relationship quality).

At the end of the interview, participants were invited to attend a Pre-Test Education session. Those who declined were asked if they could be contacted for follow-up interviews, and contact their partners for potential recruitment for the partner part of the study.

In addition to the information already being collected (cancer-specific and general distress), the following will be administered: plans to disclose test results to the partner, strain of testing process on marital relationship, perceived constraints in talking to the partner, and marital satisfaction.

A Pre-Test Standard Education Session was conducted within the next four weeks among consenting subjects. Written consent was obtained from all subjects prior to the education session. A genetic counselor conducted all sessions, under the supervision of a medical oncologist and Dr. Schwartz.

Determination of Carrier Status, Genetic Counseling/Disclosure of Genetic Test Results, Cancer Prevention/Surveillance Recommendations. Mutation status tests and counseling were offered to all high risk individuals. At the participant=s discretion, a spouse or companion may be present at this meeting (controlled for in statistical analysis).

Follow-up Genetic Counseling was conducted by telephone about two weeks after disclosure of mutation status (only for those subjects who received test results).

Follow-up Telephone Interviews was conducted at 1-, 6- and 12-months after the individual genetic counseling session for subjects who received results of mutation testing. Subjects who declined to be tested were contacted for follow-up at these time points after the Pre-Test Education date of their index family member (proband). Telephone interviews were conducted (by blinded interviewers) to reassess measures included in the ongoing study.

Data collection procedures: Partners. After partners gave written consent for the telephone interview, they were administered surveys by phone at the same times as the testing participants were administered surveys: baseline, 1-, 6- and 12-months after the individual genetic counseling session for partners of subjects who received the test results.

Telephone interviews were supervised by Dr. Schwartz (participants) and Dr. Manne (partners). Telephone interviews were used successfully in ongoing data collection. At the end of the interview, women were invited to attend a Pre-Test Education session. Those who declined were asked if we could contact them for follow-up interviews.

Measures given to both partners, all time points: 1) Cancer-Specific Distress: The Impact of Events Scale (IES) is a 21-item scale that has intrusion and avoidance subscales; 2) Hopkins Symptom Checklist-25: a 25-item Likert scale indicating severity of anxiety and depression; 3) Dyadic Adjustment Scale: widely-used 32-item scale assessing marital satisfaction (Kagan et al., 1991). Subscales include cohesion, satisfaction, affection and consensus; 4) Marital Strain: 2 items assessing marital strain during testing process. Additional measures for women: 1) Baseline: a) whether decision to seek genetic testing was discussed with partner; b) whether subjects plan to disclose test results to partners; c) constraints in talking with partner about breast cancer and testing (5 items; adapted from Lepore's (Lepore et al., 1996) scale); 2) Post-notification: a) whether or not test results were disclosed; b) partner supportive/unsupportive responses during discussion; c) if no disclosure was made, whether or not disclosure is planned; d) constraints. Additional measures for partners: 1) Baseline: a) whether decision to test was discussed; 2) Post-notification: a) whether test results were disclosed; 3) All time points: Cancer-specific distress/concerns (in addition to IES): worries about testing effects on: a) children; b) childbearing decisions; c) worry about possible cancer diagnosis; d) worry about caregiving responsibilities should the participant be diagnosed with cancer.

Data Analysis Plan: Hypothesis 1: The two dependent measures (partner IES, HSCL) will be examined individually (i.e., univariate analyses) and together (multivariate analyses) using multifactor fixed effect

ANOVA and ANCOVA with blocking on family (participants are from hereditary families). The 1-, 6-, and 12-month post-notification responses will be analyzed separately with baseline response used as a covariate. The two dependent variables will be analyzed together using repeated measures ANOVA, with the between groups factor as test group (Mc, Nc, Td). The independent variables included: (1) whether the participant has cancer, and; (2) whether the partner was present during counseling and disclosure of test results. We will also explore the influence of other relevant sociodemographic variables and interactions (e.g. partner education, ethnicity). These tests of interaction effects identify variables that modify the impact of testing among husbands of carriers, noncarriers, and test decliners. Hypothesis 2: The analysis of DAS scores of couples will be analyzed separately using the same ANOVA and ANCOVA approaches outlined above for partner distress. For the second question, we will examine the influence of marital satisfaction at baseline on post-notification marital satisfaction of participants and partners. High and low marital satisfaction will be determined by a median split on the baseline DAS variable. A repeated measures MANOVA will be conducted separately for the two indicators of marital satisfaction (general marital satisfaction and marital strain). Baseline general marital satisfaction will be entered into the analysis. We will examine differences in marital satisfaction over time between the three groups (Mc, Nc, Td) using ANOVA approaches outlined above. It is predicted that carriers and husbands with low marital satisfaction at baseline will evidence more marital dissatisfaction post-notification than carriers with high marital satisfaction or noncarriers and test decliners with low or high marital satisfaction. Hypothesis 3: This analysis will be conducted on women who are carriers. We will use separate regression analyses with participant=s psychological distress and marital satisfaction at 1-, 6- and 12-months post-notification as dependent variables. We enter first into the equation sociodemographic variables which predict distress and marital satisfaction. Next, we will enter: 1) baseline distress, 2) intrusive thoughts about cancer, 3) constraints in talking with the partner, 4) the interaction term between intrusive thoughts and constraints (centered). It is anticipated that the interaction term will be significant. Power Analysis: The design of the study is essentially one of clustered sampling, since study subjects are identified on the basis of family membership. Outcome measures will be considered at the four time points. Between participant factors will include test result (carrier, noncarrier, decliners). An interaction effect would reveal a different course of psychological responses over time.

## Results

We have not completed all data analyses at this time. In this Final Report, we will report changes in distress and marital dynamics across the 6 month-post disclosure time period as well as the associations between partner support and unsupportive responses on participant distress levels.

In terms of test results, test results were classified as "carrier" if a deleterious, risk-conferring mutation was identified in BRCA 1 or 2. Carriers could be affected persons (affected carriers) or unaffected relatives where a mutation had been found in the family and the person tested positive for the genes (unaffected carriers). Results were classified as "non carriers" if unaffected relatives (persons who did not have cancer) who tested negative for the mutation in their family.

### Participant Enrollment

448 eligible genetic testing participants were approached at Georgetown University for interest in participating in the spouse study. 304 (68%) of these participants gave consent. 283 partners were approached at FCCC for interest in the spouse study. 209 (74%) gave informed consent. Our initial estimates of accrual onto the spouse study were as follows: 410 participants and 370 partners. Thus, our enrollment was 25% less for participants than anticipated, and 43% less than anticipated for partners. The reason for this was that we initially estimated that five women per week would be eligible for participation, but there were only two to three eligible

participants identified each week: In 1998, we had 2 eligible wives per week; in 1999, three per week; in 2000, 2 per week; and in 2001, 3 per week.

225 genetic testing participants have completed baseline surveys, 178 testing participants have completed one-month follow ups, 183 participants have completed 6-month follow ups, and 165 participants have completed one year follow ups. 184 partners have completed baselines, 148 partners have completed one month follow ups, 143 partners have completed 6 month follow ups, and 130 partners have completed one year follow-ups.

There were 23 patient drops at Time 1(8%); 22 drops at Time 2 (8.4%); 5 drops at Time 3 (2%); and 6 drops at Time (2.9%). There were 8 partner drops at Time 1 (2.6%); 23 at Time 2 (7.8%); 11 at Time 3 (3.9%); 4 at Time 4 (1.6%).

The mean age of genetic testing participants was 50 years. 95% were Caucasian. 98.6% of the persons tested were female, 3.2% were males. The mean age of the partners was 53 years. 91% were Caucasian. Of the couples who were married, the median length of the marriage was 22 years.

***Aim 1: Impact of testing on distress and marital outcomes***

Means and standard errors for the main variables of interest are reported in the table below. Participant and partner scores are reported separately. Lower scores for cancer-specific IES, psychological distress, and state anxiety indicate better psychological profiles. Higher scores for marital adjustment indicated a greater satisfaction with the marital relationship.

| | **Participants** | | | **Partners** | | |
|---|---|---|---|---|---|---|
| | **Affected Carrier** | **Unaffected Carrier** | **Non-Carrier** | **Affected Carrier** | **Unaffected Carrier** | **Non-Carrier** |
| **HSCL total** | | | | | | |
| Baseline | 43.87(17.7) | 37.3(9.1) | 38.8(13.2) | 35.85(9.0) | 34.09(6.6) | 32.85(4.1) |
| 1 Month | 39.53(14.4) | 33.7(7.1) | 34.9(12.0) | 36.00(10.2) | 35.90(9.2) | 33.71(4.2) |
| 6 Month | 39.37(15.2) | 32.9(5.9) | 34.3(8.9) | 37.08(9.8) | 35.27(9.8) | 33.86(6.5) |
| **IES Total** | | | | | | |
| Baseline | 17.00(18.21) | 14.00(18.45) | 21.33(16.63) | 17.00(18.2) | 14.00(18.1) | 7.66(11.1) |
| 1 month | 21.57(21.23) | 13.62(21.35) | 12.69(15.59) | 16.18(15.63) | 12.00(12.11) | 5.16(8.0) |
| 6 month | 23.29(23.24) | 14.07(15.57) | 12.82(17.17) | 15.91(20.92) | 7.66(7.96) | 2.00(2.3) |
| **Marital Satisfaction** | 110.8(18.92) | 119.7(12.34) | 116.0(16.2) | 124.9(10.3) | 120.7(16.6) | 116.3(20.1) |
| Baseline | 104.8(27.23) | 123.6(6.6) | 111.4(17.1) | 125.1(11.9) | 122.6(16.3) | 113.5(15.8) |
| 1 month | 113.6(22.1) | 119.5(16.4) | 116.4(18.0) | 120.2(13.8) | 121.5(18.3) | 111.1(19.9) |
| 6 month | | | | | | |
| **Marital Strain** | | | | | | |
| Baseline | .60 (.94) | .27 (.65) | .00 (1.2) | .14 (.36) | .36 (.50) | .78 (1.4) |
| 1 month | .30 (.66) | .27 (.65) | .00 (.64) | .28 (.72) | .45 (.82) | .00 (.00) |
| 6 month | .60 (1.3) | .90 (1.2) | .00 (.00) | .50 (1.2) | .63 (1.3) | .00 (.00) |

To date, our findings suggest that testing participants who receive negative results decreases in IES scores over the six month period after disclosure of test results, while participants notified that they are carriers of the BRCA 1 or BRCA 2 gene do not show a significant decrease in IES scores over the same time period. Partners did not

evidence significant changes in either general psychological distress or cancer-specific distress (IES). General marital satisfaction and cancer-specific marital strain did not evidence changes

*Aim 2: Associations between partner responses and participants' distress*

Bivariate correlations were conducted to examine the association between partner responses and participants' distress levels at each time point. At baseline, results suggested that participants who rated higher levels of relationship strain associated with the genetic testing process reported significantly more general distress ($r$ = .31, $p < .001$). Participants who rated their partners as responding in an unsupportive manner also reported more general distress ($r = .54$, $p < .001$), and greater use of protective buffering was also associated with more distress ($r = .51$, $p < .001$). Participants who shared their concerns with their partners rated lower distress ($r = -.28$, $p < .001$), and participants who rated their spouses as more "supportive" of his/her decision to undergo the testing process were less distressed ($r = -.27$, $p < .001$). The same pattern of associations was found when cancer-specific distress (Impact of Event Scores) were evaluated.

The same set of correlations were conducted for the one month post-disclosure data. Results were consistent with the baseline findings, with three exceptions. Participants who rated their partners as responding in an unsupportive manner reported more general distress ($r = .26$, $p < .01$), and greater use of protective buffering was also associated with more distress ($r = .37$, $p < .001$). The same pattern of associations was found when cancer-specific distress (Impact of Event Scores) were evaluated. The two exceptions were: relationship strain, how supportive the spouse was during the discussion about the genetic testing results, and the degree to which the participant shared her concerns with her partner and s/he was comfortable sharing his/her concerns with the partner.

Finally, the same set of correlations were conducted for the six month post-disclosure data. At six months, partner unsupportive responses ($r = .48$), patient protective buffering of partners ($r = .51$) and degree of relationship strain ($r = .37$) were all significantly associated with general distress. The same pattern of associations were found for anxiety and cancer-specific distress. Interestingly, more sharing of concerns with partners was associated with more distress. This finding is probably explained by the fact that participants who were still talking about their genetic testing experience, were still upset by the experience.

Overall, our findings suggest that partner negative responses and participant efforts to protect their partners from their worries are both associated with more distress among genetic testing participants. In further analyses, we will determine whether partner ratings of their own responses also predicted testing participants' distress. We will also determine whether partner negative responses played a more detrimental role in participant distress among participants receiving "bad news" (e.g., mutation carriers).

## KEY RESEARCH ACCOMPLISHMENTS

- Data collection for baselines and follow-ups are completed
- There are a few outstanding one year follow ups that will be completed
- Analyses are underway for the first publication
- All data have been transferred to Fox Chase (e.g., genetic testing status).

## REPORTABLE OUTCOMES

The one-month follow-up data were presented at the Society of Behavioral Medicine meeting in Seattle, Washington, in March 2001. We plan on publishing three manuscripts from this data set.

## CONCLUSIONS

Our analyses thus far suggest that BRCA 1/ 2 testing does not have an impact on partner distress or relationship satisfaction. Our results for genetic testing participant outcomes post-disclosure are consistent with results reported by the Georgetown University group in the Journal of Clinical Oncology (Schwartz et al., 2002) (which is to be expected, as we utilized the same participants). Among unaffected relatives, we found that participants who received definitive negative test results exhibited significant reductions in distress compared with participants who received positive test results.

We found that the degree to which couples talk about, and feel comfortable talking about, their feelings and concerns about genetic testing, at the time of the testing and shortly thereafter, is associated with lower psychological distress for participants in these programs. Partner support and encouragement for the genetic testing decision is also associated with less distress on the part of participants. However, if participants are still sharing their concerns six months after disclosure, this is associated with increased distress.

Finally, we found that partner unsupportive responses at all time points were associated with more distress among participants and that attempts on the part of participants to protect or "buffer" their partner from their own feelings and worries, were also associated with more distress. These findings are consistent with Dr. Manne's other research on couples coping with cancer. Relationship strain associated with the genetic testing process was associated with more participant distress at baseline and at the 6 month follow up.

NOTE TO PROGRAM:

In our last progress report, the DOD commented about the study sample size. We had anticipated our final sample size to be 410 patients and 370 spouses. Our actual sample size was 304 patients and 209 spouses. Although this sample size was not what we originally anticipated, these final numbers were obtained by approaching every eligible participant referred to us from Georgetown's Testing Program. We were, of course, limited to the size of the GUMC Genetic Testing Program. We expanded our eligibility criteria to include same sex partners as well as male genetic testing participants in an effort to increase accruals. However, our sample size was smaller than expected, but this was not due to lack of effort on our part.

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None to date.

## LIST OF PERSONNEL RECEIVING PAY FROM THE RESEARCH EFFORT

Ruth Bingler
Jennifer Connors
Nicole Fasanella
Jessica Ray
Heather Simoes
Jeanne Schueller
Summer Sherburne

Dr. Manne contributed effort, but did not receive salary support from this project.

## APPENDICES

None